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EXAMINER

KHAN, OMAR A

ART UNIT PAPER NUMBER

3762

DATE MAILED: 02/21/2003


Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/748,791

Applicant(s)

LINDH ET AL. 

Examiner

Omar A Khan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 13-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 13-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 12/4/2002 have been fully considered but they are not persuasive. Taylor clearly discloses displaying for the user one or more suggested pulse generator settings, namely "shock" and "no-shock" in the abstract and throughout the specification. Cohen discloses numerous pacemaker modes (VVI, VVR, VVT, VVTR) and pulse generator settings dependent on the QRS intervals throughout the specification.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Further, Struble explicitly discloses the relationship between QRS duration or length and RBBB and LBBB patients in column 12, lines 16-22, which Cohen uses to generate an effective pacing regimen.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 1-3, 15 and 16 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Taylor et al (US Patent No 6,304,773).

3. Claims 1-3 and 14-16 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sweeney et al (US Patent Pub No 2002/0016550).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-3 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen (US Patent No 5,174,289). Cohen discloses all of the claimed limitations but does not explicitly speak to a programmer displaying the one or more pulse generator settings and performing the algorithms for pulse generator settings. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the pacing system and method of Cohen to include a programmer that allowed for displaying the one or more pulse generator settings and performing the algorithms for pulse generator settings since it was well known in the art to use a programmer to provide the medical practitioner or caregiver with increased control and feedback of the patient's status and pulse generator settings for timely reaction in case of pacer error or emergency and maintenance of accurate patient files.
2. Claims 4-6 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen (US Patent No 5,174,289) in view of Struble (US Patent No 6,070,101).

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Cohen discloses all of the claimed limitations but does not speak explicitly to measuring the difference between left and right ventricular contractions. Struble teaches a multiple channel cardiac pacing system having a pacing algorithm using the difference between left and right ventricular contractions for providing an indication of the presence of right or left bundle branch block. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the pacing system and method of Cohen to include measuring the difference between left and right ventricular contractions, as taught by Struble for providing a secondary indication of a treatable arrhythmia (such as right or left bundle branch block) and providing assurance of the presence of such an arrhythmia before initiating a potentially uncomfortable, unnecessary, and even damaging pacing regimen.

3. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen (or Taylor or Sweeney). Cohen (or Taylor or Sweeney) discloses all of the claimed limitations but does not explicitly speak to receiving a request to display one or more pulse generator settings and displaying an estimated time to complete executing the algorithm. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the pacing system and method of Cohen (or Taylor or Sweeney) to include receiving a request to display one or more pulse generator settings and displaying an estimated time to complete executing the algorithm since it was well known in the art to use a programmer to interface with the caregiver or medical practitioner and display or provide the caregiver or medical practitioner the data being analyzed, algorithm output, or estimated algorithm execution time to provide for a comprehensive review of the pulse generator in case of errors or an emergency and also allow

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the medical practitioner to document the pulse generator settings and patient status in the patient files.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 6,442,433 to Linberg

US Patent Publication 2002/0123672 to Christopherson et al

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Omar A Khan whose telephone number is (703) 308-0959. The examiner can normally be reached on M-F 9AM-6PM.

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The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0873.



2/14/03

Omar A Khan

February 14, 2003



GEORGE R. EVANISKO
PRIMARY EXAMINER
2/14/3